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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,038	04/26/2000	Gerhard Bienhaus	P101614-00001	9496

7590 08/28/2003

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/558,038	Bienhaus
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 16, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *13-35* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *13-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2003 has been entered.

Specification

2. Claims 13 and 34 have been amended.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 13-35 are rejected under 35 U.S.C. 103(a) as being obvious over Reeve (U.S. Patent 5,523,231) (June 4, 1996) in view of Ansfield (U.S. Patent 5,910,446) (June 8, 1999).

Reeve teaches a method of isolating nucleic acid from biological compartments of a fluid sample (Abstract) comprising the steps of:

a) incubating the sample in a sample processing vessel with magnetic particles which magnetic particles are capable of binding with the biological compartments (Abstract and Figures 1-2, especially step 1, and Examples 1-8);

b) positioning at least one magnet towards the sample processing vessel such that the magnet holds the magnetic particles against an inside wall of the sample processing vessel by magnetic force (Figures 1-2, especially step 4);

c) removing the remaining fluid, from which the biological compartments have been separated, from the sample processing vessel (Figures 1-2, especially step 5);

d) introducing a second fluid into the sample processing vessel (Figures 1-2, especially step 6);

e) resuspending the magnetic particles in the second fluid by eliminating the magnetic force which held the magnetic particles against the inside wall of the sample processing vessel, and shaking the sample processing vessel (Column 4, lines 31-36);

f) lysing the biological compartments to form a lysis mixture (Claims 4-5); and

g) isolating the nucleic acids from the lysis mixture (Column 4, lines 36-44 and Claims 4-5).

Reeve teaches a method, wherein essentially all of the magnetic particles have a diameter of 2.8 micrometer to 200 micrometer (Column 2, lines 59-61 and Column 8, lines 52-53).

Reeve teaches a method, wherein the isolation step comprises immobilizing the nucleic acids on the magnetic particles (Figures 1-2).

Reeve teaches a method, wherein the nucleic acids to be isolated are transferred to a vessel which is configured to receive a pipette (Column 4, lines 39-44).

Reeve teaches a method, wherein the magnetic force is eliminated by separating by a sufficient distance the at least one magnet from the outside wall of the sample processing vessel (Column 4, lines 33-36).

Reeve teaches a method, wherein the processing vessel containing the sample is shaken during at least a portion of the incubation step to facilitate binding (Column 4, lines 31-36).

Reeve teaches a method, wherein the magnetic force is eliminated and the sample processing vessel is shaken simultaneously (Column 4, lines 31-36 and Example 6 and Column 5, lines 36-38).

Reeve teaches a method, wherein the steps a) to g) are repeated until the biological compartments have reached a desired level of purity (Claims 4-5).

Reeve teaches a method, wherein the fluid sample is a body fluid which is blood (Example 8, especially column 11, lines 45-50).

Reeve teaches a method, wherein the nucleic acids are present and detected in the sample reaction vessel in a block throughout the removing, resuspending and lysing steps (Examples 6-8 and Claims 4-5).

Reeve teaches a method, wherein the lysis mixture is warmed to a temperature around room temperature or higher (Example 7, column 10, lines 65-67).

Reeve teaches a method, wherein the lysis mixture is cooled under conditions that make it possible to isolate or hybridize the nucleic acids to be isolated or detected (Example 5).

Reeve teaches a method of dissolving and redissolving the components of a nucleic acid isolation mixture in the absence of the magnetic force (Column 4, lines 33-36, Column 5, lines 19-24, Column 5, lines 38-42 and Column 6, lines 23-24).

Reeve does not teach shaking the sample to carry out dissolving and redissolving although it is well known in the art to an ordinary practitioner to carry out such a routine step.

Ansfield teaches shaking the sample to carry out dissolving and redissolving (Column 3, lines 2-4).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method of shaking the sample to carry out dissolving and redissolving of Ansfield into the nucleic acid extraction of Reeve, since Ansfield states, "Preferably the mix is shaken to ensure that the salt dissolves (Column 3, line 2)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the method of shaking the sample to carry out dissolving and redissolving of Ansfield into the nucleic acid extraction of Reeve, in order to improve the quantity of extracted target nucleic acid from a

biological sample. An ordinary practitioner would have been motivated to combine and substitute the method of shaking the sample to carry out dissolving and redissolving of Ansfield into the nucleic acid extraction of Reeve, in order to achieve the express advantages, as noted by Ansfield, of a process that ensures the dissolution of salts and other components in an isolation reaction mixture.

Reeve in view of Ansfield do not teach the specific weight of the magnets which is in the range of 0.5 g to 5 g and warming of the lysis mixture to a temperature of about 70 degree to 95 degree centigrade.

However, it is *prima facie* obvious that the selection of the specific weight of the magnet and warming of the lysis mixture to a particular temperature represent routine optimization with regard to the sizes of the biological compartments and nucleic acid molecules to be isolated and the requirement of isolation speed which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of the specific weight of the magnet and warming of the lysis mixture to a particular temperature performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Response to Amendment

5. In response to amendment, previous 102(e) and 103(a) rejections are hereby withdrawn. However, new 103(a) rejection has been included.

Response to Arguments

6. Applicant's arguments with respect to pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner,

August 18, 2003